

Exhibit B



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CDER Drug and Biologic Approvals for Calendar Year 2006 Updated through July 31, 2006

New Drug Application (NDA) Approvals:

NDA Number	Proprietary Name	Established Name	Applicant	Chemical Type	Re Class
N021838	Boniva	ibandronate sodium	Hoffmann-La Roche	3	
N021852	Ticlonex	cabotriptene; betamethasone dipropionate	LEO Pharma	3	
N021612	Lipofen	fencofibrate	Cipher	3	
N021812	Men's Rogaine	minoxidil	Pharmacia and Upjohn	3	
N021938	Sutent	sunitinib malate	Pfizer	1	
N021247	Aeroplan	fluticaside HFA	Forest Labs	3	
N021526	Ranexa	ranolazine	CV Therapeutics	1	
N021868	Exubera	insulin (dDNA Origin)	Pfizer	3	
N021908	Amittiza	lubiprostone	Sunovion	1	
N021313	Clarinet-D 12 Hour	desloratadine; pseudoephedrine sulfate	Schering	5	
N021026	Vusion	milnacipran hydrochloride	Barrier Therapeutics	3	
N021920	napiroxen sodium	napiroxen sodium	Banner Pharmaceuticals	3	
N021871	Loestrin 24 Fe	norethindrone acetate; ethinyl estradiol; ferrous fumarate	Warner Chilcott	3	

N021632	Exicid	anidulafungin	Veeva	1
N021849	Zegerid	omeprazole, sodium bicarbonate	Santarus	4
N021336	Emsem	sellegrin hydrochloride	Somerset Pharma	3
N021676	YAZ	drospirenone, ethinyl estradiol	Parfex	2
N021892	Omniprep	sodium phosphate monobasic monohydrate, sodium phosphate dibasic anhydrous	Salix	3
N021850	Zegerid with Magnesium Hydroxide	magnesium hydroxide, omeprazole, sodium bicarbonate	Santarus	3,4
N021980	Fluorescein	fluorescein	Alcon Research	5
N021483	Geodon	zipsadone hydrochloride	Pfizer	3
N022010	Septocaine	artesian hydrochloride, epinephrine	Depoco	5
N021514	Drytrans	methylenedinitrate	Noven Pharma	2,3
N021897	Vivitol	naltrexone	Alkermes	3
N021903	NeoProfen	ibuprofen lysine	Farnason-IL, LLC	2
N021790	Duoogen	decabine	MGI Pharma	1
N020808	Solodyn	minocycline hydrochloride	Medica	3
N021928	Chantix	varenicline	Pfizer	1
N021641	Azitol	resigline mesylate	TEVA	1
N021860	Serfen	fluoxetine hydrochloride	Warner Chilcott	3
N021338	Jansys	fentanyl iontophoresis transdermal system	ALZA	3
N021764	brimonidine tartrate	brimonidine tartrate	Alcon	5
N021840	Seasonique	levonorgestrel/ethinyl estradiol and ethinyl estradiol	Duramed	3
N020805	Oracea	doxycycline	CollaGene	3
N021426	Ornithope	somatropin (rDNA origin)	Sandoz	5
N021959	Orgred ODT	prednisolone sodium phosphate	BioMarin	3
N021729	Abilify Discomelt	Aripiprazole	Otsuka	3
N021254	Adair HFA	Fluticasone propionate and salmeterol xinafoate	GlaxoSmithKline	3
N021479	Zelapar	selegiline hydrochloride	Valent	3

N021610	Opana	oxycodone hydrochloride	Endo	3
N021611	Opana	oxycodone hydrochloride	Endo	3
N021976	Prezista	darunavir	Tibco	1
N021986	Sprevel	dasatinib	Bristol-Myers Squibb	1
N021717	lidocaine, tetracaine	lidocaine, tetracaine	Zen	4
N021937	Avipila	efavirenz, emtricitabine, tenofovir disoproxil fumarate	Glend Sciences	4
N021949	budesonide	budesonide	AstraZeneca	5
N021529	Implanon	etonogestrel	Organon USA	3
N021502	Avohelios SX	avobenzene, cinnamyl, octylstyrene	L'Oreal	1,4
N021929	Symbicort	budesonide, formoterol fumarate dihydrate	AstraZeneca	4
N021958	Lemist AT	terbinafine	Novartis	8
N021910	Normocarb HF	sodium chloride, magnesium chloride hexahydrate, sodium bicarbonate	Dialysis Solutions	3
N021925	Duetact	pioglitazone hydrochloride, glimepiride	Takeda Global	4
N021946	Xolegel	ketoonazole	Barrier Therapeutics	3
N021872	Keppra	levetiracetam	UCB	3

N021612 Lipofen was tentatively approved on 7/15/2004
N021764 Brimonidine Tartrate was tentatively approved on 2/28/2005

New Drug Application (NDA) Tentative Approvals

NDA Number	Proprietary Name	Established Name	Applicant	Chemical Type
N021915	ondansetron hydrochloride	ondansetron hydrochloride	Baxter	3

N021915 Ondansetron was tentatively approved on 5/26/2006

New Drug Application (NDA) Tentative Approvals under the President's Emergency Plan for AIDS Relief (PEPFAR):

NDA	Chemical	Ref
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Number	Proprietary Name	Established Name	Applicant	Type	Class
N021943	efavirenz; lamivudine; zidovudine	efavirenz; lamivudine; zidovudine	Aurobindo	4	
N021939	lamivudine; zidovudine; nevirapine	lamivudine; zidovudine; nevirapine	Aurobindo	4	
N021944	lamivudine; zidovudine; abacavir sulfate	abacavir sulfate; lamivudine; zidovudine	Aurobindo	4	

N021943 lamivudine 150mg/zidovudine 300mg Fixed-Dose Tablets co-packaged with efavirenz 600mg Tablets was tentatively approved on 3/06/2006 under N021939 lamivudine 150mg/zidovudine 300mg/nevirapine 200mg Tablets was tentatively approved on 6/30/2006 under PEPFAR.
N021944 lamivudine 150mg/zidovudine 300mg/Copekted with abacavir sulfate 300mg Tablets was tentatively approved on 07/26/2006 under PEPFAR.

Biologic License Application (BLA) Approvals:

BLA Number	Proprietary Name	Proper Name	Applicant	Review Classification
BL 125141	Myozyme	alpha-glucosidase alfa	Genzyme	P, O
BL 125156	Tucentis	ranibizumab	Genentech	P
BL 125151	Eprex	idursulfate	Shire Human Genetic Therapies	P, O

NDA Chemical Type:

- 1 - New molecular entity
- 2 - New ester, new salt, or other noncovalent derivative
- 3 - New dosage form
- 4 - New combination
- 5 - New formulation or new manufacturer
- 7 - Drug already marketed, but without an approved NDA
- 8 - OTC switch

Review Classification:

- P - Priority Review - Significant improvement compared to marketed products, in the treatment, diagnosis, or prevention of a disease.
- S - Standard Review - Products that do not qualify for priority review.
- O - Orphan Designation - Pursuant to Section 526 of the Orphan Drug Act (Public Law 97-414 as amended).